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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/773,121 | 02/05/2004 | Charmaine K. Harris | 1023-270US02 | 3255 |

28863 7590 09/07/2005

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| EXAMINER | |
|---|---|
| ALTER, ALYSSA M | |
| **ART UNIT** | **PAPER NUMBER** |
| 3762 | |

DATE MAILED: 09/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/773,121 | HARRIS ET AL. | |
| | Examiner | Art Unit | |
| | Alyssa M. Alter | 3762 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *05 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/15/04 & 2/22/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Double Patenting*

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

1. Claims 1-43 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-43 of copending Application No. 10/718,038 (US Patent Publication 20050049663). This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 1-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mamo et al. (US 6,847,849) in view of and Cross, JR (US Patent Publication 20050182470 A1).

Mamo et al. discloses a dilator with a conical distal tip and sheath as depicted in figures 8a-8c, in addition to a needle and a guide wire for application of neurostimulation therapy. "The needle is adapted to be withdrawn over the guide wire, and the dilator is adapted to be inserted over the guide wire proximal end to locate the guide wire within the dilator body lumen and to be advanced distally over the guide wire through the insertion path to dilate the insertion path to the dilator diameter" (col. 3, lines 10). The process is displayed in figure 9a.

In addition, figure 9b "shows inserting and guiding a needle 36, e.g., a foramen needle 36, comprising a hollow needle body and a stylet or obdurator 40 within the needle body lumen, to the sacral nerve site in accordance with steps 50 and 52"(col. 12, lines 20-24).

"The dilator body 47 is preferably conductive, and the dilator sheath 49 is preferably non-conductive but may bear radiopaque and visually observable depth marks 51 along its length to facilitate radiographic imaging when it is extended into the patient's body" (col. 10, lines 58-63).

"The dilators 42 can be metal or plastic"(col. 7, lines 5). Since the dilator, which includes both the dilator body and dilator sheath, can be constructed from plastic, the sheath and dilator are both deformable. In addition, according to Columbia University Press Dictionary, polyethylene is a "widely used plastic". Therefore, since the dilator can be constructed from a plastic, it would have been obvious to create the dilator from polyethylene.

Mamo et al. discloses the claimed invention except for the oblong cross-section. Cross, JR teaches that it is known to use an oval cross-section for the purpose of stimulating the spinal column through the delivery of paddle style leads. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the dilator, dilator sheath and needle as taught by Mamo et al. with the oblong or oval cross-section as taught by Cross, JR, in order to utilize available space in the spinal column area to stimulate the patient and to accommodate a paddle style medical leads commonly used to stimulate a patient's spinal column area.

Further, Cross, JR teaches it is known to use oblong or oval cross-section to deliver paddle style leads. Cross, JR also discloses that "the cross section of the lumen 208 is such that the width is greater than the height. A typical width for the lumen cavity to receive a paddle style lead 50 may be 2.5 mm to 12 mm (0.1" to 0.5") with a height of 1.4 mm to 2.0 mm (0.055" to 0.079")" (page 5, paragraph 83). Therefore, if the lumen had a 12mm width and a 2.0mm height, which is within the range disclosed by Cross, JR, the width would be more than three times the height. Additionally, the needle is "an epidural, Tuohy or modified Tuohy needle"(page 5, paragraph 84).

***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

1. Simonson (US Patent Publication 2003/0083688 A1) discloses a configured and sized cannula.

2. DeWindt et al. (US 6,146,371) discloses an oval-shaped cardiac cannula.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alyssa M. Alter whose telephone number is (571) 272-4939. The examiner can normally be reached on M-F 9am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Alyssa M Alter
Examiner
Art Unit 3762

JEFFREY R. JASTRZAB
PRIMARY EXAMINER
9/2/5